



May 17, 2005

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Ortho Molecular Products Inc.
3017 Business Park Drive
P.O. Box 1060
Stevens Point, WI 54481
715.342.9881 Phone
800.332.2351
715.342.9866 Fax
orthomolecularproducts.com

Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

MAY 25 2004

Dear Sir/Madam:

This letter will serve as notification, pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.93, that Ortho Molecular Products, Inc. is using the following claim on its label (see attached labels on page 2).

Name of Manufacturer: Ortho Molecular Products, Inc.
3017 Business Park Drive
P.O. Box 1060
Stevens Point, WI 54481

Statement Text: Cardiovascular Health, Daily Essentials

Dietary Ingredients: Vitamin B6 (as Pyridoxine HCl USP), Folic Acid, Vitamin B12 (as Methylcobalamin), Betain (Trimethyl Glycine), Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

Dietary Supplement Name: Cardio B

As required, enclosed are two photocopies of this notification.

I certify that the information presented and contained in this notice is complete and accurate, and that Ortho Molecular Products, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,

A handwritten signature in cursive script that reads "Melissa Slager".

Melissa Slager
Document Control / Training Manager
Ortho Molecular Products

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Ortho Molecular Products Cardio B
5/17/2005
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Attachment of Cardio B Labels

Suggested Use: As a dietary supplement, 1 or more capsules per day or as recommended by your health care professional. Formulated to be free of allergens derived from: Gluten, corn, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. If you are pregnant or nursing, consult your physician before taking this product. As with all dietary supplements, some individuals may not tolerate or may be allergic to the ingredients used. Please read the ingredient panel carefully prior to ingestion. Cease taking this product and consult your physician if you have negative reactions upon ingestion. **KEEP CONTAINER TIGHTLY CLOSED. STORE AT ROOM TEMPERATURE. KEEP OUT OF REACH OF CHILDREN.** This product was sealed for your protection. Do not use if outer logoed neck seal or inner-seal are missing or damaged.

† These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.



Label ID L-OMP100-546060-C
Also Excellent for:

Daily Essentials

Dietary Supplement Product #546



CardioB

Supplement Facts

Serving Size 1 Capsule
Servings Per Container: 60

1 capsule contains	Amount Per Serving	% Daily Value
Vitamin B6 (as Pyridoxine HCl USP [†])	50 mg	2500%
Folic Acid	5 mg	1250%
Vitamin B12 (as Methylcobalamin)	1 mg	16667%
Betain (Trimethyl Glycine)	500 mg	*
* % Daily Value not established		

Other Ingredients: Natural vegetable capsules. This product may contain one or more of the following: Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose and Silicon Dioxide.

Mfg. by: Ortho Molecular Products, Inc. 3017 Business Park Drive Stevens Point, WI 54481

OrthoMolecularProducts.com

60 Capsules

Suggested Use: As a dietary supplement, 1 or more capsules per day or as recommended by your health care professional. Formulated to be free of allergens derived from: Gluten, corn, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. If you are pregnant or nursing, consult your physician before taking this product. As with all dietary supplements, some individuals may not tolerate or may be allergic to the ingredients used. Please read the ingredient panel carefully prior to ingestion. Cease taking this product and consult your physician if you have negative reactions upon ingestion. **KEEP CONTAINER TIGHTLY CLOSED. STORE AT ROOM TEMPERATURE. KEEP OUT OF REACH OF CHILDREN.** This product was sealed for your protection. Do not use if outer logoed neck seal or inner-seal are missing or damaged.

† These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Label ID L-OMP100-546120-C



Also Excellent for:

Daily Essentials

Dietary Supplement Product #546A



CardioB

120 Capsules

Supplement Facts

Serving Size 1 Capsule

Servings Per Container: 120

	Amount Per Serving	% Daily Value
1 capsule contains		
Vitamin B6 (as Pyridoxine HCl USP [®])	50 mg	2500%
Folic Acid	5 mg	1250%
Vitamin B12 (as Methylcobalamin)	1 mg	16667%
Betain (Trimethyl Glycine)	500 mg	*

* % Daily Value not established

Other Ingredients: Natural vegetable capsules. This product may contain one or more of the following: Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose and Silicon Dioxide.

Mfg. by: Ortho Molecular Products, Inc. 3017 Business Park Drive, Stevens Point, WI 54481

OrthoMolecularProducts.com